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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/670,763	09/25/2003	Richard A. Blake	ESST1000	2771

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EXAMINER	
NGUYEN, HIEP VAN	
ART UNIT	PAPER NUMBER
3626	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/670,763	BLAKE ET AL.	
	Examiner	Art Unit	
	HIEP NGUYEN	3626	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *25 September 2003*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-22* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-22* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Status

1. Claims 1-22 have been examined.

Claim Rejections - 35 USC § 112, Second Paragraph

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claim 16 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

4. The limitation in claim 16 recites "subjecting the stored patient identification information…to anonymity constraints". The term "subjecting" renders the claim indefinite.

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

6. Claims 1-22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Fey et al. (US PGPub. 20020052761) in view of Davies et al. (US PGPub. 20030046114.)

7. With respect to Claim 1, Fey et al. teaches a computer-implemented method for processing patient medical information for storage, comprising:

a. separating the patient medical information into a first information portion that includes at least information identifying a patient and information identifying a physician of the patient , and a second information portion that includes clinical and demographic information for the patient, and the information identifying the physician, but that does not include information identifying the patient ('761; Para 022-0023; 0026);

b. generating a unique code for the patient which does not identify the patient ('761; Para 0023, lines 1-3 unique identifier);

c. placing the unique code into the first and second information portion ('761; Para 0023);

d. providing the first information portion for storage in a first storage ('761; Para 0028: client identifier); and

e. providing the second information portion for storage in a second storage, separate from the first storage ('761; Para 0028: lines 8-17).

However, Fey et al. does not disclose the information identifying a physician of a patient. Davies et al. further discloses the information identifying a physician of a patient ('114; Para 0051-0052; 0054; Example 1, 2, 3 on Paras. 0103-109.)

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the teachings of Fey et al. and Davies et al. to integrate the clinical genetic information.

Claim 13 is rejected as the same reason with Claim 1.

8. With respect to Claim 2, the combined art teaches the method of claim 1, Fey et al. further discloses wherein the first storage is a first database system and the second storage is a second database system, separate from the first database system, the method further comprising:

f. placing the first information portion in one or more first database records ('761; Para 0031 record for unique client identifier);

g. placing the second information portion in one or more second database records ('761; Para 0031 records of genetic test);

h. and wherein, providing the first information portion includes providing the one or more first database records for storage in the first database system, and providing the second information portion includes providing the one or more

second database records for storage in the second database system ('761; Para 0023, Para 0028, para0029; 0031).

Claim 12 is rejected as the same reason with Claim 2.

9. With respect to Claim 3, the combined art does not disclose wherein the clinical and demographic information includes at least one ICD (International Classification of Diseases) code.

However, Official Notice is taken that the ICD code has been known as a basis for physician practice in hospital and healthcare. Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention to combine the teachings of Fey et al. related to the physician practice of ICD code.

Claim 10, 14 are rejected as the same reason with Claim 3.

10. With respect to Claim 4, the combined art teaches the method of claim 1, Fey et al. further discloses wherein the clinical and demographic information includes genetic information ('761; Para 0022-genetic test.)

Claims 11, 15 are rejected as the same reason with Claim 4.

11. With respect to Claim 5, the combined art teaches the method of Claim 1, Davies et al. further disclose comprising:

i. providing at least one third party subscription to contents of the second storage ('114; Para 0052.)

j. permitting a third party holding a third party subscription to search the second storage using clinical trial search criteria ('114; Abstract: search criteria) ;

k. obtaining search results including a count of second information portions in the third party search which satisfy the clinical trial search criteria; and providing the clinical trial search criteria and the search results to an administrator process ('114; Abstract.)

Claim 18 is rejected as the same reason with Claim 5.

12. With respect to Claim 6, the combined art teaches the method of claim 1, Davies further discloses comprising the administrator process searching the second storage using the clinical trial search criteria, obtaining search results including one or more unique codes and information identifying one or more physicians of patients for whom the one or more unique codes were generated'114; Para 0066.)

13. With respect to Claim 7, the combined art teaches the method of claim 1, Fey et al. further discloses comprising: associating a physician process with a

physician; and providing the one or more unique codes of the search results to the physician process ('761; Para 0026);

the physician process:

obtaining from the first storage information identifying patients for whom the one or more unique codes of the search results were generated; and using the information identifying patients for whom the one or more unique codes of the search results were generated, recruiting patients for a clinical trial ('761; Para 0027-collecting demographic information.)

14. With respect to claim 8, it is system claim which repeats the same limitations of claims 1 the corresponding method claims, as a collection of elements as opposed to a series of process steps. Since the teachings of Fey et al./Davies et al. disclose the underlying process steps that constitute the method of claim 1, it is respectfully submitted that they provide the underlying structural elements that perform the steps as well. As such, the limitations of claim 8 are rejected for the same reasons given above for claims 1.

15. With respect to Claim 9, the combined art teaches the system of Claim 8, Fey et al. further discloses in combination with means for generating the unique code ('761; Para 0022-0023.)

16. Claim 16 is rejected as the same reason with Claim 1.

Davies et al. further discloses means for searching the second data storage using clinical trial search criteria; means for receiving search results from the second data storage in response to the clinical trial search criteria ('114, Abstract.)

17. With respect to Claim 17, the combined art teaches the combination of claim 16.

Fey et al. further discloses wherein the at least one additional processor is an administrator processor associated with the second storage, and the search results include: PIDS for patients whose clinical and demographic information satisfies the clinical trial criteria ('761; Para 0022); and PHIDS for physicians of the patients whose clinical and demographic information satisfies the clinical trial criteria ('761; Para 0026.)

18. Claim 19 is rejected as the same reason with Claim 1.

Fey et al. further discloses subjecting the stored patient identification information and the stored clinical and demographic information to anonymity constraints;

according at least one subscriber a privilege level with respect to the clinical and demographic information denying identification of patients associated with the clinical and demographic information ('761; Para 0024. The Examiner interprets anonymity constraints considered as risk factor assigning unique identifier);

Davies et al. further discloses permitting the subscriber to search the clinical and demographic information according to search criteria for a clinical trial protocol; and providing results to the subscriber ('114; Abstract.)

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the teachings of Fey et al. / Davies et al. related to anonymity constraints and search criteria for clinical trial protocol.

19. With respect to Claim 20, the combined art teaches the method of claim 19, Fey et al. further discloses wherein the anonymity constraints include:
providing a unique code for a patient which does not include identification of the patient ('761; Para 0022-0023);
appending the unique code for the patient to the patient identification information for that patient and to the clinical and demographic information for the patient; and storing including storing the patient identification information with appended unique code in a first storage, and storing the clinical and demographic information with appended unique code in a second storage separate from the first storage ('761; Para 0024, 0027.)

20. With respect to Claim 21, the combined art teaches the method of claim 19, Fey et al. further discloses wherein the search results provided to the subscriber include a number of hits but do not include unique codes ('761; Para 0024: positive and negative response as compared with number of hits.)

21. With respect to Claim 22, the combined art teaches the method of claim 19, Fey et al. further discloses including: according an administrator of the second storage a privilege level with respect to the clinical and demographic information denying identification of patients associated with the clinical and demographic information, but permitting retrieval of unique codes ('761; Para 0076);
permitting the administrator to search the clinical and demographic information according to the search criteria for a clinical trial protocol; and
providing results to the administrator which include unique codes ('761; Para 0077.)

Conclusion

22. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

23. Any inquiry concerning this communication or earlier communications from the examiner should be directed to HIEP NGUYEN whose telephone number is (571) 270-5211. The examiner can normally be reached on Monday through Friday 7:30AM-5:00PM.

24. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jerry O'Connor can be reached on (571) 272-6787. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

25. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or (571) 272-1000.

/HIEP NGUYEN/
Examiner, Art Unit 3626
August 29, 2008

/Gerald J. O'Connor/
Supervisory Patent Examiner
Group Art Unit 3626